

## **REMARKS**

### **Status of the Claims**

Claims 1-7, 9-13, 15-17, 19, 22, 25, 28 and 30-58 were pending.

Claims 1-7, 9-13, 30-32, and 34-54 stand allowed.

Claims 15-17, 19, 22, 25, 28, 33 and 56-58 stand rejected.

Claims 15-17, 19, 22, 25, 28, 33 and 56-58 are canceled herein.

Claims 1, 2, 32, 34, 37, 41, and 52 are amended herein.

Claims 59-61 are new claims.

Reconsideration is respectfully requested.

Applicants gratefully acknowledge that the Examiner had found claims 1-7, 9-13, 30-32, and 34-54 to recite allowable subject matter. Claims 15-17, 19, 22, 25, 28, 33 and 56-58 stand rejected. All rejected claims are canceled herein, rendering rejections to those claims moot.

Allowed claims 1, 2, 32, 34, 41, and 52 are amended, and Claims 59-61 are new claims. It is noted that Claim 55 previously was numbered as "claim 34," but there were two claims numbered "claim 34" – thus, Claim 55 is identical in scope to previous (2<sup>nd</sup>) claim 34 and it is understood this is an allowed claim.

Below, Applicants first discuss the amendments to the allowed claims, then the new claims.

### **Allowed Claims 1, 2, 32, 34, 37, 41, and 52**

With regard to the allowed claims, this amendment corrects minor matters of form.

Claim 1 was amended to delete the term "for parental administration" in the preamble. This phrase recites a statement of intended use which is non-limiting. Thus, the statement has no impact on claim scope and is superfluous. Applicant has thus deleted the term to avoid ambiguity.

Claim 1 also has been amended to recite that the epothilone analog may be a salt or isomer of a compound according to formula I. Salts are supported by the specification at page 7, lines 13-20, and isomers are supported at page 8, lines 6-10.

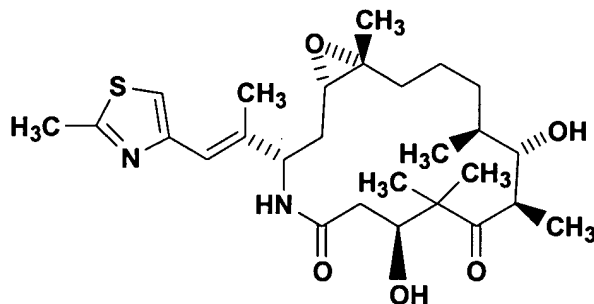
Similarly, claims 2, 32, 34, and 41 were amended to (where present) delete the preamble phrase "for parenteral administration" and to refer to salts and isomers. As with

claim 1, these amendments are supported by the specification at page 7, lines 13-20, and page 8, lines 6-10.

Claims 37 and 52 are amended to replace the reference to "epothilone" with "epothilone analog." The compounds of Formula I herein are epothilone analogs, *e.g.*, lactam analogs of the epothilones. Thus, these claims have been amended for accuracy and to maintain consistency in the claim terminology as the specification and claims throughout refer to epothilone analogs.

New Claims 59-61

Claim 59 is a new claim directed to the process for making a lyophilized epothilone analog having the formula,



wherein the epothilone analog is first dissolved in a solvent mixture comprising tertiary-butanol and water, then lyophilized (*i.e.*, dried under vacuum).

Applicant submits this claim should be allowed for essentially the same reasons that claims 1-7, 9-13, 30-32, and 34-54 stand allowed. The prior art does not disclose this process for lyophilizing this epothilone analog using a mixture of tertiary-butanol and water solution which provides particular advantages as detailed in the specification herein at page 12, line 16 through page 13, line 9.

Further, this claim is supported at page 3, lines 6-8 of the specification which states that according to the present invention, "the epothilone analog is initially solubilized with a mixture of tertiary-butanol and water and then lyophilized under optimized conditions."

New claims 60 and 61 depend upon claim 59 and thus, applicant submits these claims should be allowed for the same reasons as claim 59. It is noted that claim 61 is similar in scope to allowed claims 51 and 53, though dependent upon claim 59 rather than claims 2 and 34, respectively.

**Response to Office Action**

Applicant submits that the rejections asserted in the Office Action do not apply to any of the claims now pending. The Office Action had rejected claims 15-17, 19, 22, 25, 28, 33 on the ground that these were composition of matter claims which the Office Action had argued were obvious in view of US Pat. 6,689,802, disclosing crystalline forms of the epothilone analog recited in the present claims. While applicant disagrees with such reasoning (for reasons previously set forth), those claims were canceled, without prejudice, and new claims reciting a process are presented, which thus do not implicate the concerns raised in the Office Action.

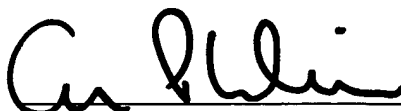
**Fees**

Although three new claims are added, more than three claims are canceled. It is not believed that any additional fees are due. However, if it is determined that an additional fee is due, the Commissioner is authorized to charge same to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

**SUMMARY**

It is believed that the above amendments place the entire application in condition for issuance. The Examiner is invited to contact the undersigned if it is believed a telephonic communication would expedite the prosecution of this application.

Respectfully submitted,



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